

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



(19)



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11)

EP 0 911 049 A1

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:  
28.04.1999 Bulletin 1999/17

(51) Int Cl.<sup>6</sup>: A61M 16/04

(21) Application number: 98307997.1

(22) Date of filing: 01.10.1998

(84) Designated Contracting States:  
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE  
Designated Extension States:  
AL LT LV MK RO SI

(71) Applicant: **Smiths Industries Public Limited  
Company**  
London, NW11 8DS (GB)

(72) Inventor: **Pagan, Eric**  
Hythe, Kent CT21 6DA (GB)

(30) Priority: 16.10.1997 GB 9721840

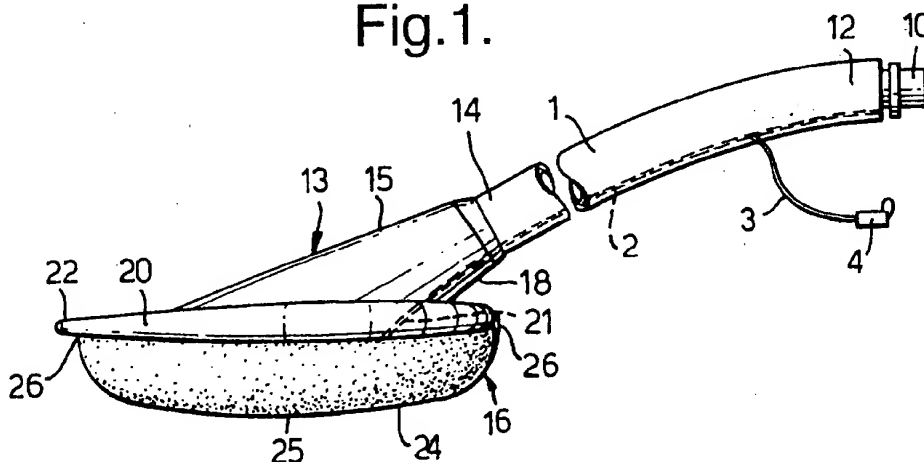
(74) Representative: **Flint, Jonathan McNeill et al**  
765 Finchley Road  
London NW11 8DS (GB)

### (54) Laryngeal mask assemblies

(57) A laryngeal mask airway has a foam cuff 16 formed on the patient surface of a plate 20 attached at the patient end 14 of a tube 1. The cuff 16 is of a self-skinning foam so that the skin 24 of the foam forms the outer surface of the cuff and seals with the plate 20. An

air lumen 2 extruded along the tube 1 opens at one end into the interior of the cuff 16 and at the other end connects with an air line 3. The cuff 16 can be compressed for insertion and removal by applying suction to the air line 3.

Fig.1.



EP 0 911 049 A1

## Description

[0001] This invention relates to laryngeal mask assemblies of the kind comprising a tube with a mask portion at its patient end, the tube opening into the centre of the mask portion and the mask portion including a mount member joined with the patient end of the tube and an outwardly-projecting plate member.

[0002] It is common practice to use an airway known as a laryngeal mask or airway for administering anaesthetic and ventilation gases to a patient. These airways comprise a tube with an inflatable mask or cuff at one end, the tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. Laryngeal masks are described in, for example, US 5355879, US 5305743, US 5297547, US 5282464, GB 2267034, US 5249571, US 5241956, US 5303697, GB 2249959, GB 2111394, EP 448878, US 4995388, GB 2205499, GB 2128561 and GB 2298797. WO 98/16273 describes a laryngeal airway with a foam pad that is squeezed to compress it for introduction and that gradually expands when in position.

[0003] Laryngeal masks have several advantages over endotracheal tubes, which are longer and seal with the trachea below the vocal folds. One problem with laryngeal mask airways, however, is that it is difficult to provide the cuff, which is of relatively complex shape, at low cost.

[0004] It is an object of the present invention to provide an improved laryngeal mask assembly.

[0005] According to one aspect of the present invention there is provided a laryngeal mask assembly of the above-specified kind, characterised in that the assembly includes a cuff formed of a foam material attached with the plate member, that the outer surface of the cuff being provided by a skin of the foam, the skin being sealed with the plate member, and that the assembly includes an air passage opening into the cuff by which suction can be applied to the cuff to compress it for insertion.

[0006] The air passage is preferably provided at least in part by a lumen extruded along the tube. The skin of the foam may be sealed around an edge of the plate member by welding. The assembly may include a cuff of foam extending on both sides of the plate member. The air passage may be connectable with the bore through the tube such that the cuff is inflated slightly during positive ventilation.

[0007] A laryngeal mask airway assembly according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation view of the assembly with the cuff expanded;

Figure 2 is a side elevation view of the patient end

of the assembly with the cuff compressed;

Figure 3 is an end view of the patient end of the assembly;

Figure 4 is a partly-sectional side elevation view of the patient end of an alternative assembly in a compressed state; and

Figure 5 is an end view of the patient end of the assembly of Figure 4.

[0008] With reference first to Figures 1 to 3, the assembly comprises a bendable tube 1 of a plastics material, such as PVC, with a coupling 10 at its machine end 12. The tube 1 is curved along its length and has a mask portion 13 attached at its patient end 14.

[0009] The tube 1 is extruded with a small bore lumen 2 within its wall. The lumen 2 is connected towards the machine end of the assembly to an air line 3, which is terminated with a connector 4. The opposite, patient end of the lumen 2 opens into the mask portion 13.

[0010] The mask portion 13 comprises a mount member 15 and a cuff member 16. The mount member 15 is moulded from a bendable plastics material, such as PVC. The mount member 15 has a hollow cylindrical sleeve 18 at its rear end, in which the forward, patient end 14 of the tube 1 is inserted and joined. A substantially flat plate 20 with a generally elliptical or egg-shape outline projects outwardly of the sleeve 18 at an angle of about 30°, at the patient end of the mount 15. An air vent hole 21 extends through the thickness of the plate 20 and communicates with the lumen 2 on the machine side of the plate. The forward end of the plate 20 is provided with a small projecting tip 22 to aid insertion and location of the patient end of the assembly.

[0011] The cuff member 16 is a ring or annulus with the same shape as the periphery of the plate 20 and with a hollow centre 23 through which the tube 1 opens at the patient end of the assembly. The cuff member 16 is formed entirely from an open cell foam material, such as polyurethane, having a self skinning characteristic, so that a skin 24 forms during curing of the foam material and provides the external surface of the cuff itself, that is, the surface that contacts patient tissue during use. The cuff 16 is formed and attached with the patient (anterior) surface of the plate 20 in a simple one-step operation. The mount member 15 is loaded in a mould (not shown) with the patient side surface of the plate 20 facing into a cavity having the desired shape of the expanded cuff. The foam material is then injected in liquid form into the cavity so that it flows over the surface of the plate 20. When the foam has cured sufficiently, the mount member 15 is removed. The foam attaches to the plate 20 and, where it is exposed, forms the impervious skin 24. Although the drawings show the expanded patient face 25 of the cuff 16 as being of a relatively simple, convex shape, it can be easily made in considerably

more complex shapes, simply by appropriately shaping the cavity in the mould. The cuff 16 is shaped so that it forms an effective seal with the pharynx or hypopharynx.

**[0012]** To ensure a gas-tight seal between the plate 20 and the cuff 16, it is preferable for the skin 24 of the cuff to be welded or otherwise sealed to the plate around its outer periphery 26 and around its inner periphery 27 around the hollow centre 23 of the cuff.

**[0013]** The lumen 2 opens into the foam of the cuff 16 via the air vent 21 in the plate 20 and, since the foam of the cuff has open cells, it enables the cuff to be deflated or compressed by attaching a syringe to the connector 4 and withdrawing air from the cuff via the lumen 2 and the air line 3. This sucks the skin 24 of the cuff 16 closer to the plate 20, as shown in Figure 2, giving the cuff a slimmer profile for insertion and removal from the patient. This ensures that the cuff 16 remains fully compressed during insertion and that it can be rapidly expanded when correctly positioned. Because the cuff can also be fully deflated or compressed after use, it makes removal easier and less traumatic than if the cuff remained in its expanded state.

**[0014]** With reference now to Figure 4, there is shown a similar assembly having a cuff member 16' extending over both surfaces of the plate 20' of the mount member 15', the expanded shape of the cuff being shown in broken outline. The edges of the cuff 16' overlap the edges of the plate 20' around its circumference. In this example, the skin 24' of the cuff 16' is welded around the periphery 27' of the centre 23' on the patient side of the plate. In its natural shape, as shown by the broken line, the cuff 16' forms a thick layer over the patient (anterior) and machine (posterior) sides of the plate 20'. When deflated to the position shown, the cuff 16' is pulled close to the patient and machine sides of the plate 20' for insertion and removal.

**[0015]** The interior of the cuff member 16, 16' could be arranged to communicate with the main bore of the tube 1' so that, when the patient is being ventilated by positive pressure, the interior of the cuff is inflated slightly each cycle by the ventilation gas so as to form a better seal with the surrounding tissue. The arrangement by which this is achieved could be as described in EP 0072230A where the connector on the air line is removably connectable to a port opening into the machine end coupling.

rial attached with the plate member (20, 20'), that the outer surface of the cuff (16, 16') is provided by a skin (24) of the foam, the skin (24) being sealed with the plate member (20, 20'), and that the assembly includes an air passage (21, 2, 3) opening into the cuff (16, 16') by which suction can be applied to the cuff to compress it for insertion.

2. A laryngeal mask assembly according to Claim 1, characterised in that the air passage is provided at least in part by a lumen (2) extruded along the tube (1).
3. A laryngeal mask assembly according to Claim 1 or 2, characterised in that the skin (24) of the foam is sealed around an edge (26, 27, 27') of the plate member (20, 20') by welding.
4. A laryngeal mask assembly according to any one of the preceding claims, characterised in that the assembly includes a cuff (16') of foam extending on both sides of the plate member (20').
5. A laryngeal mask assembly according to any one of the preceding claims, characterised in that the air passage (21, 2, 3) is connectable with the bore through the tube (1) such that the cuff (16, 16') is inflated slightly during positive ventilation.

## Claims

1. A laryngeal mask assembly comprising a tube (1) with a mask portion (13) at its patient end (14), the tube opening into the centre (23, 23') of the mask portion, the mask portion (13) including a mount member (15) joined with the patient end (14) of the tube (1) and having an outwardly-projecting plate member (20, 20'), characterised in that the assembly includes a cuff (16, 16') formed of a foam mate-

Fig.1.

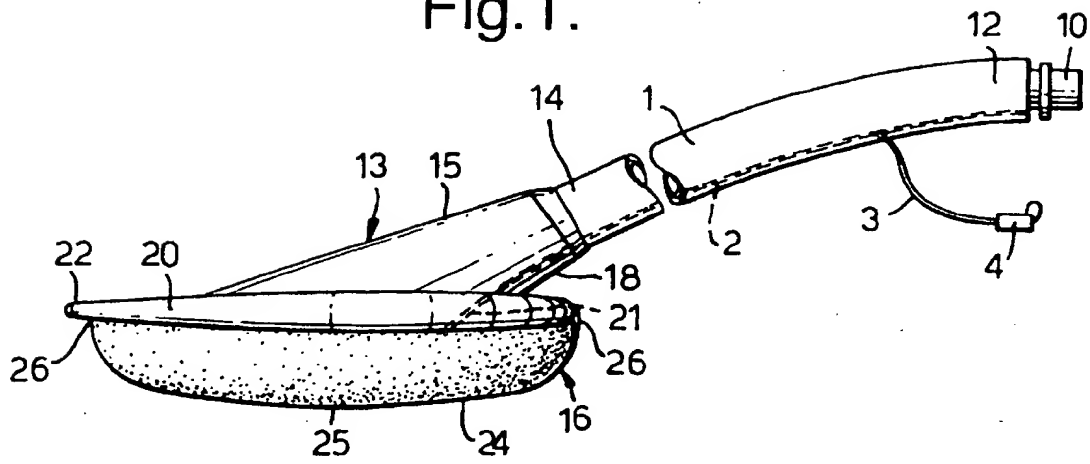


Fig.2.

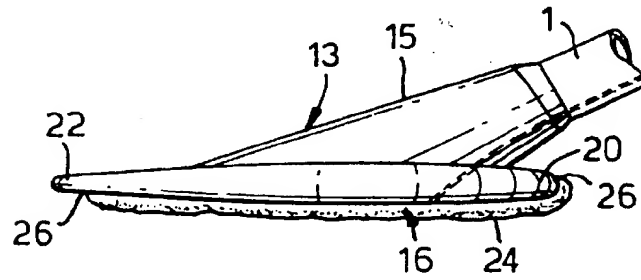


Fig.3.

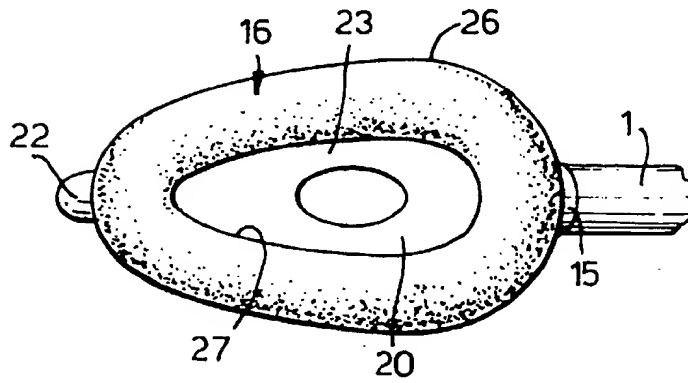


Fig.4.

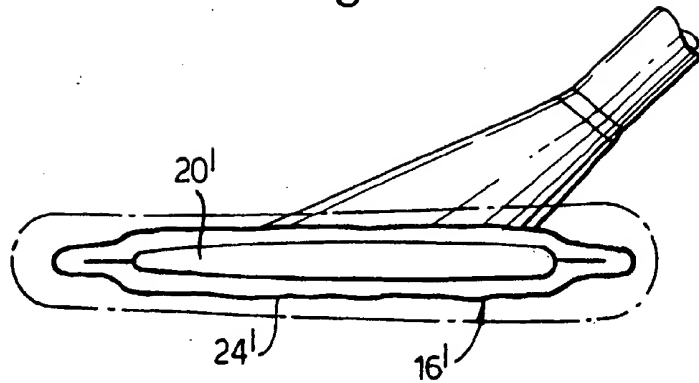
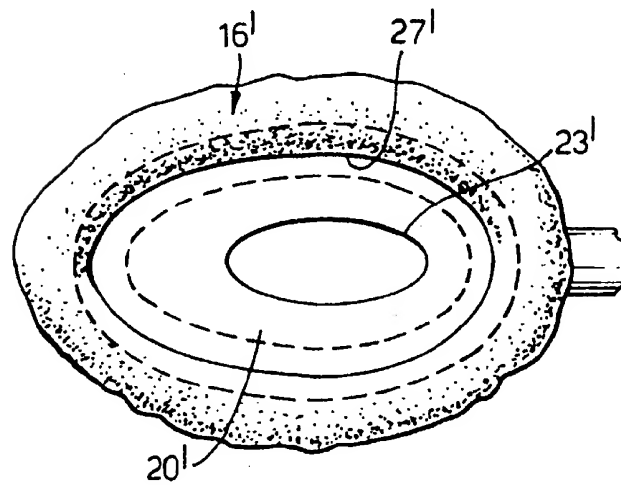


Fig.5.





European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			FP 98307997.1
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
A, D	<u>GB 2298797 A</u> (SMITHS INDUSTRIES PUBLIC LIMITED COMP.) 18 September 1996 (18.09.96), the whole document. --	1	A 61 M 16/04
A	<u>WO 95/33506 A1</u> (BRAIN, A.) 14 December 1995 (14.12.95), fig. 1, page 7, lines 15-23, page 10, lines 13-23. --	1, 2	
A, D	<u>EP 0072230 A1</u> (BIVONA SURGICAL INSTRUMENTS, INC.) 16 February 1983 (16.02.83), fig. 1, abstract, page 7, line 3 - page 9, line 18. --		
A	<u>GB 1308882 A</u> (KAMEN, J.M.) 07 March 1973 (07.03.73), fig. 2, 5, page 2, line 109 - page 3, line 54. --		TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
A	<u>DE 4339706 C1</u> (KEIM, M.) 27 April 1995 (27.04.95), fig. 1, column 7, lines 28- 66. ----		A 61 M
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
VIENNA		01-02-1999	LUDWIG
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application I : document cited for other reasons & : member of the same patent family, corresponding document	

EPO FORM 1503 01.82 (P0401)



This annex lists the patent family members relating to the patent documents cited in the above-mentioned search report. The members are as contained in the EPO/US INPADOC file on 8. 2.1999.  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

[illegible]

For more details about this annex see Official Journal of the European Patent Office, No. 12/82.

THIS PAGE BLANK (USPO)

Fig.1.

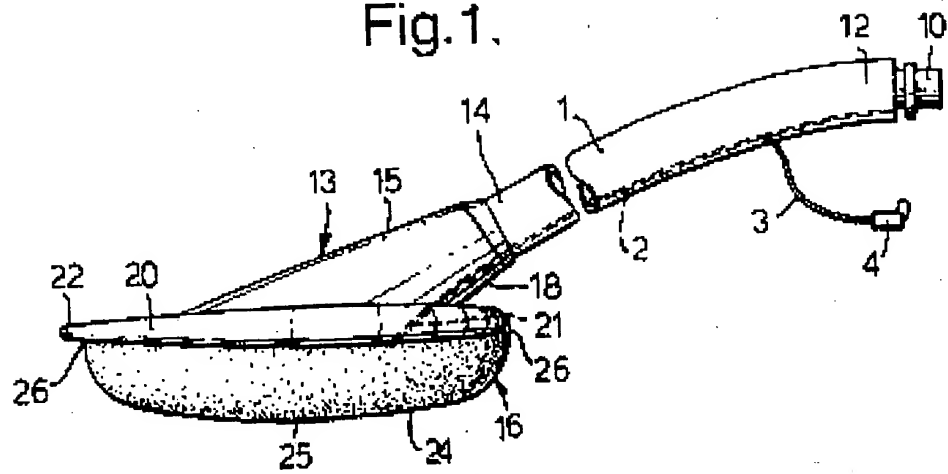


Fig.2.

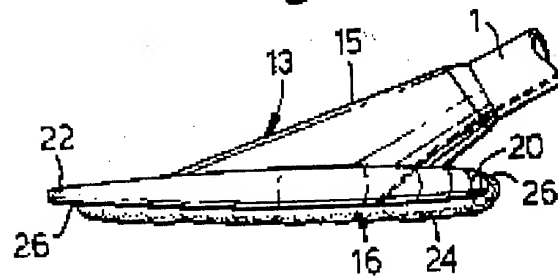


Fig.3.

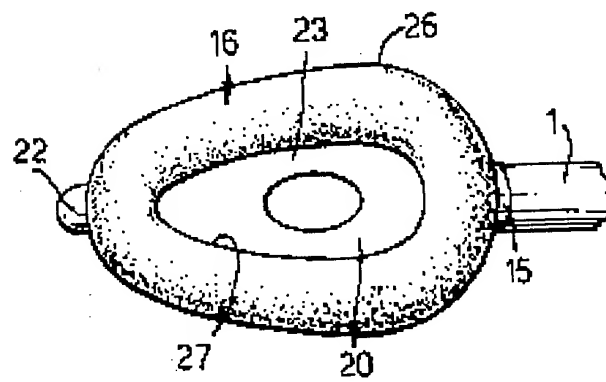


Fig.4.

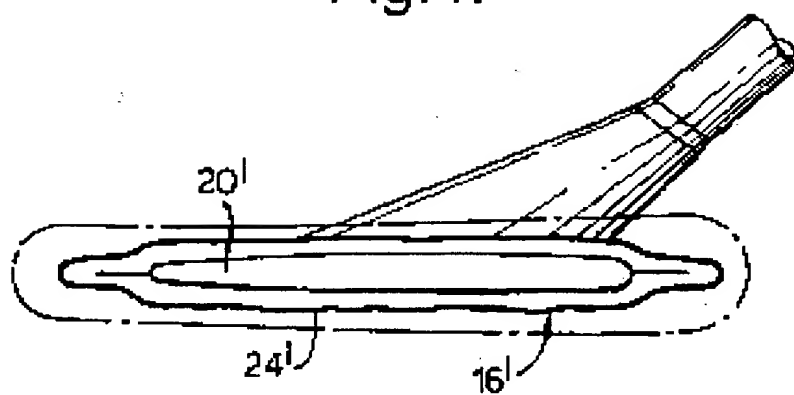


Fig.5.

